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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/750,079	Confirmation No. 1878
Applicant	:	Sepehr Fariabi	
Filed	:	December 31, 2003	
Title	:	HIGH STRENGTH MEMBER FOR INTRACORPOREAL USE	
Art Unit	:	3774	
Examiner	:	Paul B. Prebilic	
Docket No.	:	ACSG-66757 (G0970USC5)	
Customer No.	:	24201	March 30, 2009

Mail Stop Appeal Brief - PATENTS
Commissioner for Patents

APPEAL BRIEF

Dear Sir:

This Appeal Brief is being filed pursuant to the Notice of Appeal that was filed on January 30, 2009.

INTRODUCTION

The present invention relates to a stent, and more particularly pertains to a stent that has exceptionally high strength yet has excellent ductility, properties which are typically mutually exclusive to one another. Consequently high strength stents are usually self-expanding devices while ductile materials are used for balloon expandable stents. The stent is formed by a process (e.g. cold working steps, tensioning, annealing, age hardening, etc.) that enables a particular alloy, although ductile, to be used in an **expandable** stent application, wherein the material must be plastically deformed in order to achieve its expanded state within a coronary artery. Similar alloys had previously been exclusively used in self-expanding applications. The present application, U.S. Serial No. 10/750,079 was filed December 31, 2003 and is a continuation of application that was filed 4/2/98 that issued as USPN 6,736,843, which is a continuation of an application that was filed 3/28/97 and that issued as USPN 6,482,166 which in turn is a continuation of an application that was filed 7/25/94 and that issued as USPN 5,636,641.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is ABBOTT CARDIOVASCULAR SYSTEMS INC. (formerly Advanced Cardiovascular Systems, Inc., the assignee of record), 3200 Lakeside Drive, Santa Clara, CA 95054, which is a division of Abbott Laboratories, 100 Abbott Park Road, Abbott Par, Illinois 60664-3500. This application was originally assigned by the inventor, SEPEHR FARIABI to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment executed September 21, 1994, which was recorded by the US Patent Office on October 3, 1994 beginning at Reel 71531, Frame 0227.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

The application was originally filed with 37-85. Claims 37-85 are currently pending, are under final rejection and are being appealed. A copy of the claims being appealed is appended as Exhibit 1.

IV. STATUS OF AMENDMENTS

No amendment was filed subsequent to the final Office Action of October 31, 2008.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The rejected claims are all directed to an expandable stent formed of a particular metal alloy and requires such stent to be expandable to its radially expanded state within a coronary artery by plastic deformation.

Independent claim 37 is supported in the specification and drawings as follows:

37. A cylindrically shaped balloon expandable stent configured for use in a coronary artery (Fig. 3, # 40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27), and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expanded configuration (Fig. 7; page 16, lines 2-4)

and is plastically deformable (page 8, lines 20) from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the cylindrical elements of the stent assume the first low profile delivery configuration through compression and have an elasticity insufficient to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation (page 8, line 20).

Independent claim 44 is supported in the specification and drawings as follows:

44. A cylindrically shaped balloon expandable stent configured for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) generally aligned along a common longitudinal axis and formed from metallic alloy tubular member containing cobalt, chromium, and molybdenum, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27); and

the stent has a first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expanded configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable (page 8, line 20) from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery.

Independent claim 51 is supported in the specification and drawings as follows:

51. A cylindrically shaped balloon expandable stent configured for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of a metallic alloy containing cobalt, chromium, molybdenum and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27), the cylindrical elements having a transverse dimension of about 0.003 inch (page 13, line 30) and generally aligned along a common longitudinal axis; and

the stent has first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expanded configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable (page 8, line 20) from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the cylindrical elements of the stent have an elasticity insufficient to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation so as to be permanent (page 8, line 20).

Independent claim 52 is supported in the specification and drawings as follows:

52. A cylindrically shaped balloon-expandable stent for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising:

an interior chamber configured to receive an expandable member for plastically expanding the stent from a first low profile delivery configuration (Fig. 5; page 15, lines 1-2) to a second radially expanded configuration (Fig. 7; page 16,

lines 2-4), the second radially expanded configuration having a diameter suitable to hold open the coronary artery; and

the stent having a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29), each cylindrical element formed from tubular member of an alloy containing cobalt, chromium, molybdenum and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27), the cylindrical elements having a transverse dimension of about 0.003 inch (page 13, line 30) and generally aligned along a common longitudinal axis.

Independent claim 53 is supported in the specification and drawings as follows:

53. A cylindrically shaped balloon-expandable stent configured for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27), and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expandable configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable (page 8, line 20) from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the cylindrical elements of the stent have an elasticity insufficient to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation so as to be permanent, and the cylindrical elements having an undulating component (page 8, line 20).

Independent claim 62 is supported in the specification and drawings as follows:

62. A stent (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of an alloy containing about 28 to about 65 weight percent cobalt, about 5 to about 35 weight percent chromium, about 2 to about 40 weight percent nickel, and one alloy component selected from the group consisting of iron, manganese and tungsten (page 3, lines 15-27);

the cylindrical elements being generally aligned along a common longitudinal axis; and

the cylindrical elements having an undulating component (Fig. 13, #52; page 6, lines 20-29) which has an electrochemically polished metallic surface (page 10, line 4);

wherein the stent is plastically deformable from a first low profile delivery configuration to a second radially expanded configuration having a diameter suitable to hold open the coronary artery (page 8, line 20).

Independent claim 66 is supported in the specification and drawings as follows:

66. A stent (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of an alloy containing about 28 to about 65 weight percent cobalt, about 5 to about 35 weight percent chromium, about 2 to about 40 weight percent nickel, and an amount of molybdenum up to about 15 weight percent, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27);

the cylindrical elements being generally aligned along a common longitudinal axis,; and

the cylindrical elements having an undulating component (Fig. 13, #52; page 6, lines 20-29) which has an electrochemically polished metallic surface (page 10, line 4); and

wherein the stent is plastically deformable from a first low profile delivery configuration to a second radially expanded configuration having a diameter suitable to hold open the coronary artery (page 8, line 20).

Independent claim 77 is supported in the specification and drawings as follows:

77. A cylindrically shaped balloon-expandable stent configured for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) generally aligned along a common longitudinal axis and formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27);

the cylindrical elements having an undulating component with an electrochemically polished metallic surface (page 10, line 4);

a biocompatible coating on the electrochemically polished metallic surface of the cylindrical elements (page 10, line 5); and

the stent is plastically deformable from a first low profile configuration to a second radially expanded configuration having a diameter suitable to hold open the coronary artery (page 8, line 20);

wherein the cylindrical elements of the stent have an elasticity insufficient to allow expansion from the first low profile configuration to the second radially expanded configuration without plastic deformation so as to be permanent (page 8, line 20).

Independent claim 82 is supported in the specification and drawings as follows:

82. A cylindrically shaped balloon expandable stent configured for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29), the cylindrical elements generally aligned along a common longitudinal axis and formed from metallic alloy containing cobalt, chromium, and molybdenum, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27);

undulations that are plastically expandable (page 8, line 20) in a blood vessel for deployment therein;

the stent having electrochemically polished (page 10, line 4) tubular internal and external surfaces and a reticulated tubular structure having bounded openings for blood perfusion, the reticulated tubular structure having a continuum body (page 8, lines 12-15) made from tubing (page 9, lines 17-23); and

the stent has a first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expanded configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery (page 8, line 20).

Independent claim 83 is supported in the specification and drawings as follows:

83. A cylindrically shaped balloon expandable stent configured for use in a coronary artery (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27), and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expanded configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration (page 8, line 20), the second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the stent is formed from a tubular alloy (page 9, lines 17-23) and has a smaller unexpanded diameter before plastic expansion and an expanded diameter upon plastic expansion (page 8, line 20).

Independent claim 84 is supported in the specification and drawings as follows:

84. A cylindrically shaped balloon expandable stent configured for use in a vessel (Fig. 3, #40; page 13, lines 13-17), comprising:

a plurality of independently expandable and interconnected cylindrical elements (Fig. 13, #52; page 6, lines 20-29) formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese (page 3, lines 15-27), and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery (Fig. 5; page 15, lines 1-2) and a second radially expanded configuration (Fig. 7; page 16, lines 2-4) and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the vessel (page 8, line 20);

wherein the stent is formed by cutting voids from a member having a surface and a thickness to form a stent having integrally interconnected struts (page 9, lines 17-23), the stent being plastically deformable inside a vessel from an unexpanded diameter to an expanded diameter to hold open the vessel (page 8, line 20).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Pursuant to the Final Office Action dated October 31, 2008, the independent claims were rejected as follows:

GROUND I

Independent claims 37, 44, 53, 62, 66, 82, 83 and 84, along with claims 38-43, 45-50, 54, 56-61, 63-65, 67-76 and 85 that depend therefrom, were rejected

under 35 U.S.C. § 103(a) as obvious over Robinson et al (USPN 5,891,193) (Exhibit 2) in view of Mayer (USPN 5,824,077) (Exhibit 3).

GROUND II

Independent claims 51 and 52 were rejected under 35 U.S.C. § 103(a) obvious over Robinson et al (USPN 5,891,193) in view of Mayer (USPN 5,824,077) as applied in Ground I and further in view of Hillstead (USPN 4,856,516) or Tower (USPN 5,217,483).

GROUND III

Independent claim 77 along with claims 78-81 that depend therefrom and claim 55 that depends from claim 37 were rejected under 35 U.S.C. § 103(a) obvious over Robinson et al (USPN 5,891,193) in view of Mayer (USPN 5,824,077) as applied in Ground I and further in view of Bokros (USPN 4,300,244).

VII. ARGUMENT

Each and every claim calls for a balloon-expandable stent to be formed of a certain alloy wherein such alloy requires the stent to undergo plastic deformation in order to attain its expanded state within a coronary artery. The independent claims do not lay claim to the process by which such property is imparted but claim the structural characteristics that are inherent in the resulting stent.

GROUND I

The Examiner bases his rejection of the claims on a passage in the primary reference (col 5, lines 31-51) wherein the process is described by which the anchor, (which the Examiner characterizes as a stent) is formed. More particularly, the Examiner asserts that because the anchor is formed by bending wire, the resulting structure is plastically deformable and could be expanded to a state where there

would be no bends in the wire. While it is true that the wire is plastically deformable and the resulting structure is **ultimately** plastically deformable, there is no suggestion or teaching that the structure formed of the bent wire is capable of attaining its expanded configuration within the vessel for which it is configured for use (as is claimed) by plastic deformation. In view of the fact that the described anchor is a self-expanding device (col 3, lines 4-6), it is in fact its inherent elasticity that is relied upon for it to attain its expanded state within the artery. Once the device attains its expanded state (by elastic expansion), it cannot be plastically deformed to its expanded state, i.e. the state it is already in. The specific claim language is more particularly distinguishable as follows:

Independent claim 37 calls for:

"...wherein the cylindrical elements of the stent .... have an elasticity **insufficient** to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation."

Clearly the cited reference has an elasticity that **is** sufficient to allow its expansion to the expanded configuration.

Independent claim 44 calls for:

"...the stent .... is **plastically** deformable from the first low profile delivery configuration to the second radially expanded configuration the second radially expanded configuration having a diameter **suitable** to hold open the coronary arter..."

Since the device of the cited reference elastically expands from its low profile delivery configuration to its expanded configuration, it cannot also be plastically deformable from its low profile delivery configuration to its expanded

configuration and any further plastic expansion beyond its elastically expanded state would expand it (and the surrounding vessel wall) to an unsuitable diameter.

Independent claim 53 calls for:

"... the stent have an elasticity **insufficient** to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation..."

Again, since the cited reference teaches a structure that relies on its elasticity to expand the stent from its low profile deliver diameter to its expanded configuration, it clearly teaches away from the present invention.

Independent claims 62 and 66 call for:

"... the stent is plastically deformable from a first low profile delivery configuration to a second radially expanded configuration having a diameter suitable to hold open the coronary artery."

Because the cited reference provides for a structure that undergoes elastic expansion from its low profile diameter to its expanded configuration it cannot simultaneously be plastically deformable from its low profile diameter to its expanded configuration.

Finally, independent claims 82, 83 and 84 both call for:

"... the stent ... is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery."

Because the cited reference relies on elastic expansion to expand from its delivery diameter to its expanded configuration, it teaches away from a structure that is deformable between such diameters.

While the Examiner goes on to point out that the claimed alloy "is extremely similar" to the material listed in the primary reference and "closely related" to the material listed in the secondary reference, it is respectfully submitted that this in fact makes a case for non-obviousness. As is taught by **both** references, such alloys are for use in **self-expanding** applications due to the material's inherent elasticity. Without the proper treatment of the alloy prior to its use as is described in the patent application (e.g. cold working stages, tensioning, annealing, age hardening, etc.), it simply doesn't have the ductility that is necessary for it to undergo plastic deformation in order to expand from a delivery diameter to its expanded configuration. While the process by which such product is made is not the focus of the present patent application, the process does yield a different **structure** than what is described in the cited references. Such structure has different physical properties that unexpectedly renders a stent formed of the "similar" or "closely related" alloy compatible with balloon delivery systems.

Finally, in the "Response to Arguments," the Examiner argues that the device of the primary reference **could be** used in a coronary artery where the device is sized to expand as described. However, the cited reference teaches away from such sizing as it unequivocally calls for device to be sized so as to assume an expanded diameter that corresponds with the vessel diameter and to expand from a compressed delivery diameter by elastic expansion. Moreover, in view of the inherent elasticity of the structure that is described in the primary reference, expanding the device to "a diameter suitable to hold open the coronary artery" by plastic deformation would require its expansion to a diameter well beyond the

diameter of such artery and would therefore render it unsuitable for "use in a coronary artery" as is required by all claims.

In view of the clear and unequivocal teaching in the cited references that the "similar" alloys are for use in self-expanding applications, it is respectfully submitted that a structure formed of such alloys that requires plastic deformation to undergo expansion in a coronary artery effectively avoids obviousness.

GROUND II

The Examiner relies on the same two references as teaching a balloon-expandable stent that is formed of a specific alloy, despite the fact that both such references clearly and exclusively teach the use of similar alloys in self-expanding applications. In effect, the cited art teaches away from the present invention as the elasticity required for the described self-expanding applications is irreconcilable with the ductility required for balloon-expandable applications. There is no suggestion or teaching that the described elastic alloys can be rendered sufficiently ductile and thus suitable for a balloon-expandable stent. It is respectfully submitted that for the same reasons set forth in Ground I above, a balloon-expandable stent formed of such alloys effectively avoids obviousness.

GROUND III

The Examiner relies on the same two references as teaching a balloon-expandable stent that is formed of a specific alloy, despite the fact that both such references clearly and exclusively teach the use of similar alloys in self-expanding applications. In effect, the cited art teaches away from the present invention as the elasticity required for the described self-expanding applications is irreconcilable with the ductility required for balloon-expandable applications. There is no suggestion or teaching that the described elastic alloys can be rendered sufficiently

ductile and thus suitable for a balloon-expandable stent. It is respectfully submitted that for the same reasons set forth in Ground I above, a balloon-expandable stent formed of such alloys effectively avoids obviousness.

VIII. CLAIMS APPENDIX

See Exhibit 1.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

XI. CONCLUSION

For the foregoing reasons, it is submitted that the present invention as claimed is not obvious over any combination of the cited references and that the Examiner's rejections of claims 37-85 were therefore erroneous. Appellant respectfully requests reversal of the rejections of independent claims 37, 44, 51, 52, 53, 62, 66, 77, 82, 83 and 84 as well as all claims that depend therefrom.

Respectfully submitted,

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/Gunther O. Hanke/
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GOH:lm

LIST OF EXHIBITS

EXHIBIT	DESCRIPTION
1.	Appealed Claims
2.	U.S. Patent No. 5,891,193, Robinson et al.
3.	U.S. Patent No. 5,824,077, Mayer

EXHIBIT 1

LISTING OF CLAIMS:

37. A cylindrically shaped balloon expandable stent configured for use in a coronary artery, comprising:

a plurality of independently expandable and interconnected cylindrical elements formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese, and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery and a second radially expanded configuration and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the cylindrical elements of the stent assume the first low profile delivery configuration through compression and have an elasticity insufficient to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation.

38. The intracorporeal stent of claim 37 wherein the alloy contains about 28% to about 65% cobalt.

39. The intracorporeal stent of claim 37 wherein the alloy contains less than about 40% nickel.

40. The intracorporeal stent of claim 37 wherein the alloy contains about 5% to about 35% chromium.

41. The intracorporeal stent of claim 37 wherein the alloy contains up to about 15% molybdenum.

42. The intracorporeal stent of claim 37 wherein the alloy further comprises up to about 20% iron.

43. The intracorporeal stent of claim 37 further comprising a plurality of independently expandable cylindrical elements which are interconnected so as to be generally aligned on a common axis.

44. A cylindrically shaped balloon expandable stent configured for use in a coronary artery, comprising:

a plurality of independently expandable and interconnected cylindrical elements generally aligned along a common longitudinal axis and formed from metallic alloy tubular member containing cobalt, chromium, and molybdenum, and one alloy component selected from the group consisting of tungsten, iron and manganese; and

the stent has a first low profile configuration for delivery and a second radially expanded configuration and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery.

45. The intracorporeal member of claim 44 wherein the alloy contains cobalt in an amount of about 28% to about 65%.

46. The intracorporeal member of claim 44 wherein the alloy further comprises nickel as an alloying element in an amount of less than about 40%.

47. The intracorporeal member of claim 44 wherein the alloy contains chromium in an amount of about 5% to about 35%.

48. The intracorporeal member of claim 44 wherein the alloy contains molybdenum in an amount of up to about 15%.

49. The intracorporeal member of claim 44 wherein the alloy further comprises iron in an amount of up to about 20%.

50. The intracorporeal stent of claim 44 wherein the alloy contains about 2 weight percent nickel.

51. A cylindrically shaped balloon expandable stent configured for use in a coronary artery, comprising:

a plurality of independently expandable and interconnected cylindrical elements formed of a metallic alloy containing cobalt, chromium, molybdenum and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese, the cylindrical elements having a transverse dimension of about 0.003 inch and generally aligned along a common longitudinal axis; and

the stent has first low profile configuration for delivery and a second radially expanded configuration and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the cylindrical elements of the stent have an elasticity insufficient to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation so as to be permanent.

52. A cylindrically shaped balloon-expandable stent for use in a coronary artery, comprising:

an interior chamber configured to receive an expandable member for plastically expanding the stent from a first low profile delivery configuration to a second radially expanded

configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery; and

the stent having a plurality of independently expandable and interconnected cylindrical elements, each cylindrical element formed from tubular member of an alloy containing cobalt, chromium, molybdenum and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese, the cylindrical elements having a transverse dimension of about 0.003 inch and generally aligned along a common longitudinal axis.

53. A cylindrically shaped balloon-expandable stent configured for use in a coronary artery, comprising:

a plurality of independently expandable and interconnected cylindrical elements formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese, and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery and a second radially expandable configuration and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the cylindrical elements of the stent have an elasticity insufficient to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation so as to be permanent, and the cylindrical elements having an undulating component.

54. The stent of claim 53, wherein the undulating component has an electrochemically polished metallic surface.

55. The stent of claim 54, further comprising a biocompatible coating on the electrochemically polished metallic surface of the cylindrical elements.

56. The stent of claim 53, wherein the alloy contains about 28 to about 65 weight percent cobalt, about 5 to about 35 weight percent chromium, about 2 to about 40 weight percent nickel.

57. The stent of claim 56, wherein the alloy further contains molybdenum up to about 15 weight percent.

58. The stent of claim 53, wherein the alloy further contains molybdenum up to about 15 weight percent.

59. The stent of claim 53, wherein at least one of the cylindrical elements has an undulating component out of phase with the undulating component of at least another one of the cylindrical elements.

60. The stent of claim 53, wherein the cross-section of the undulating component of the cylindrical element has an aspect ratio of about one to one.

61. The stent of claim 53, wherein the cross-section of the undulating component of the cylindrical element has a height-to-width aspect ratio of about two-to-one.

62. A stent, comprising:

a plurality of independently expandable and interconnected cylindrical elements formed of an alloy containing about 28 to about 65 weight percent cobalt, about 5 to about 35 weight percent chromium, about 2 to about 40 weight percent nickel, and one alloy component selected from the group consisting of iron, manganese and tungsten;

the cylindrical elements being generally aligned along a common longitudinal axis; and

the cylindrical elements having an undulating component which has an electrochemically polished metallic surface;

wherein the stent is plastically deformable from a first low profile delivery configuration to a second radially expanded configuration having a diameter suitable to hold open the coronary artery.

63. The stent of claim 62, wherein at least one of the cylindrical elements has an undulating component out of phase with the undulating component of at least another one of the cylindrical elements.

64. The stent of claim 62, wherein the cross-section of the undulating component of the cylindrical element has an aspect ratio of about one to one.

65. The stent of claim 62, wherein the cross-section of the undulating component of the cylindrical element has a height-to-width aspect ratio of about two-to-one.

66. A stent, comprising:

a plurality of independently expandable and interconnected cylindrical elements formed of an alloy containing about 28 to about 65 weight percent cobalt, about 5 to about 35 weight percent chromium, about 2 to about 40 weight percent nickel, and an amount of molybdenum up to about 15 weight percent, and one alloy component selected from the group consisting of tungsten, iron and manganese,;

the cylindrical elements being generally aligned along a common longitudinal axis,; and

the cylindrical elements having an undulating component which has an electrochemically polished metallic surface; and

wherein the stent is plastically deformable from a first low profile delivery configuration to a second radially expanded configuration having a diameter suitable to hold open the coronary artery.

67. The stent of claim 66, wherein at least one of the cylindrical elements has an undulating component out of phase with the undulating component of at least another one of the cylindrical elements.

68. The stent of claim 66, wherein the alloy has been cold-worked.

69. The stent of claim 66, wherein the alloy has been age hardened.

70. The stent of claim 66, wherein the cross-section of the undulating component of the cylindrical element has an aspect ratio of about one to one.

71. The stent of claim 66, wherein the cross-section of the undulating component of the cylindrical element has a height-to-width aspect ratio of about two-to-one.

72. The stent of claim 37, wherein the cylindrical elements have an undulating component with a cross-section having an aspect ratio of about one to one.

73. The stent of claim 37, wherein the cylindrical elements have an undulating component with a cross-section having a height-to-width aspect ratio of about two-to-one.

74. The stent of claim 37, wherein the cylindrical elements have an undulating component with a cross-section having a height-to-width aspect ratio of about two-to-one to about 0.5-to-one.

75. The stent of claim 37, wherein the cylindrical elements have an electrochemically polished metallic surface.

76. The stent of claim 74, wherein the alloy has been cold-worked and age hardened.

77. A cylindrically shaped balloon-expandable stent configured for use in a coronary artery, comprising

a plurality of independently expandable and interconnected cylindrical elements generally aligned along a common longitudinal axis and formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese,;

the cylindrical elements having an undulating component with an electrochemically polished metallic surface;

a biocompatible coating on the electrochemically polished metallic surface of the cylindrical elements; and

the stent is plastically deformable from a first low profile configuration to a second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the cylindrical elements of the stent have an elasticity insufficient to allow expansion from the first low profile configuration to the second radially expanded configuration without plastic deformation so as to be permanent.

78. The intracorporeal member of claim 77 further comprising undulations being plastically expandable in a blood vessel for deployment therein.

79. The intracorporeal member of claim 78 wherein the tubular member has a reticulated tubular structure having bounded openings for blood perfusion.

80. The intracorporeal member of claim 79 wherein the reticulated tubular structure has a continuum body made from tubing.

81. The intracorporeal member of claim 80 wherein the stent has electrochemically polished tubular internal and external surfaces.

82. A cylindrically shaped balloon expandable stent configured for use in a coronary artery, comprising:

a plurality of independently expandable and interconnected cylindrical elements, the cylindrical elements generally aligned along a common longitudinal axis and formed from metallic alloy containing cobalt, chromium, and molybdenum, and one alloy component selected from the group consisting of tungsten, iron and manganese,;

undulations that are plastically expandable in a blood vessel for deployment therein;

the stent having electrochemically polished tubular internal and external surfaces and a reticulated tubular structure having bounded openings for blood perfusion, the reticulated tubular structure having a continuum body made from tubing; and

the stent has a first low profile configuration for delivery and a second radially expanded configuration and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery.

83. A cylindrically shaped balloon expandable stent configured for use in a coronary artery, comprising:

a plurality of independently expandable and interconnected cylindrical elements formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese, and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery and a second radially expanded configuration and is plastically deformable from the first low profile delivery configuration to

the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the stent is formed from a tubular alloy and has a smaller unexpanded diameter before plastic expansion and an expanded diameter upon plastic expansion.

84. A cylindrically shaped balloon expandable stent configured for use in a vessel, comprising:

a plurality of independently expandable and interconnected cylindrical elements formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese, and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery and a second radially expanded configuration and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the vessel;

wherein the stent is formed by cutting voids from a member having a surface and a thickness to form a stent having integrally interconnected struts, the stent being plastically deformable inside a vessel from an unexpanded diameter to an expanded diameter to hold open the vessel.

85. A stent as defined in claim 84, wherein said member having a surface and a thickness to form a stent is tubular.

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United States Patent [19]

Robinson et al.

[11] Patent Number: 5,891,193

[45] Date of Patent: Apr. 6, 1999

[54] **NON-MIGRATING VASCULAR PROSTHESIS AND MINIMALLY INVASIVE PLACEMENT SYSTEM THEREFOR**

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[73] Assignee: **C.R. Bard, Inc.**, Murray Hill, N.J.

[21] Appl. No.: **840,145**

[22] Filed: **Apr. 11, 1997**

Related U.S. Application Data

[62] Division of Ser. No. 643,527, May 6, 1996, Pat. No. 5,733,325, which is a continuation of Ser. No. 147,498, Nov. 4, 1993, abandoned.

[51] **Int. Cl.**[6] **A61F 2/06**

[52] **U.S. Cl.** **623/1**

[58] **Field of Search** 623/1, 12; 606/194, 606/195

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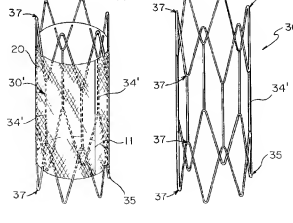
Primary Examiner—Michael J. Milano
Attorney, Agent, or Firm—Arthur Z. Bookstein

[57] **ABSTRACT**

A graft assembly for securely positioning a graft at a predetermined location across an abdominal aortic aneurysm. The assembly includes a resilient self-expanding anchor that is secured to the graft. The anchor is characterized as being at least as long as the graft, and further as being adapted to be removed or repositioned at any time prior to complete deployment in the patient.

2 Claims, 10 Drawing Sheets



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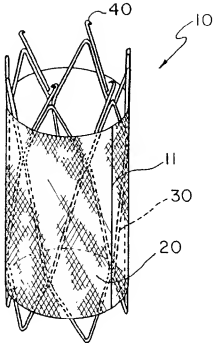

Fig. 1

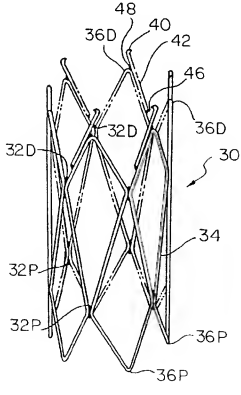

Fig. 2

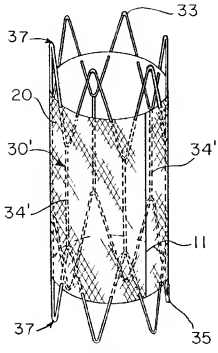

Fig.3

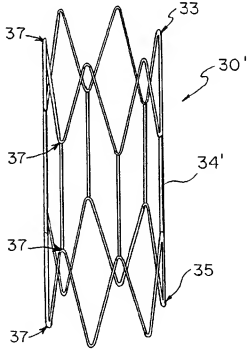

Fig.4

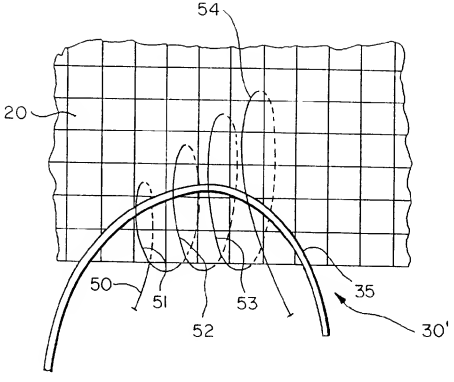

Fig.5

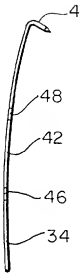

Fig.6

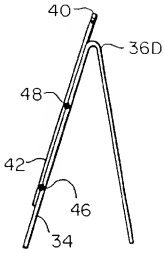

Fig.7

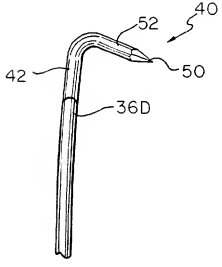

Fig.8

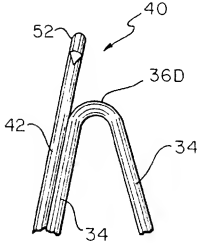

Fig.9

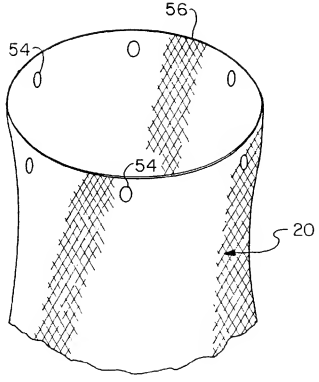

Fig. 10

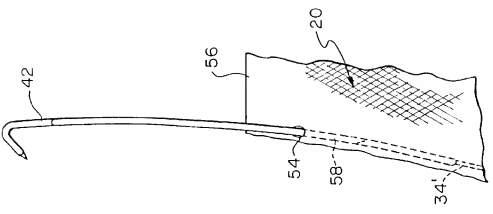

Fig. 12

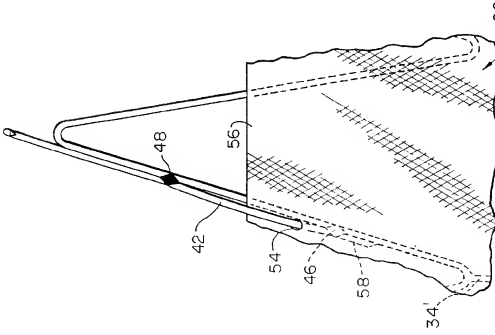

Fig. 11

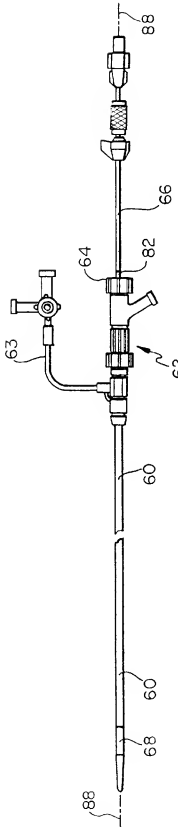

Fig. 13

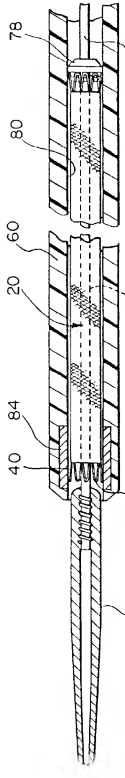

Fig. 14

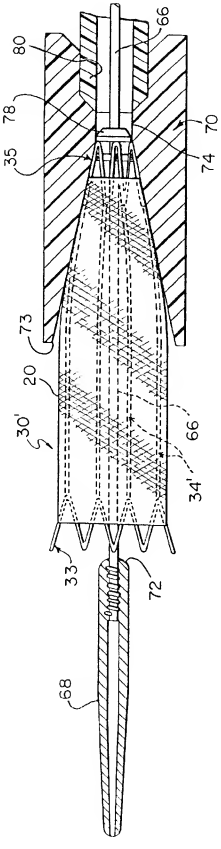

Fig. 15

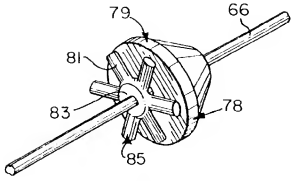

Fig. 16b

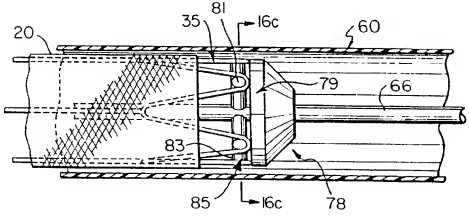

Fig. 16a

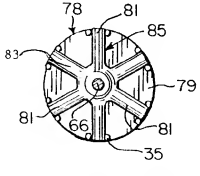

Fig. 16c

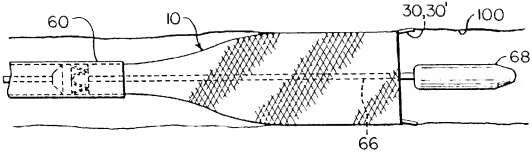

Fig. 17a

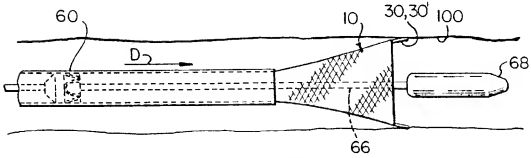

Fig. 17b

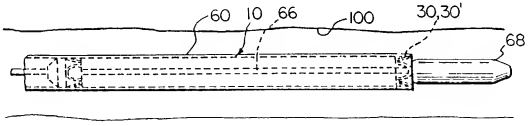

Fig. 17c

NON-MIGRATING VASCULAR PROSTHESIS AND MINIMALLY INVASIVE PLACEMENT SYSTEM THEREFOR

This is a divisional of application Ser. No. 08/643,527, filed on May 6, 1996 now U.S. Pat. No. 5,733,325, which is a file wrapper continuation of Ser. No. 08/147,498, now abandoned

FIELD OF THE INVENTION

The invention relates to devices and techniques for placing and securing a vascular graft in a predetermined location in a patient's vascular system.

BACKGROUND OF THE INVENTION

It has been long accepted practice to treat a variety of vascular disorders in a surgical procedure that involves placement of a vascular graft in a patient's vascular system. The construction and characteristic of the graft typically will be adapted to optimize its use in the specific surgical environment and condition to be treated and, accordingly, a number of different types of grafts are available. Among the most common types of vascular grafts are those formed from a woven or knitted tubular fabric as well as non-fabric tubes such as expanded polytetrafluoroethylene. Such grafts typically are placed in a patient's vascular system in a highly invasive surgical procedure. In general, the complexity of the surgical procedure required to place the graft will depend on many factors, including the location and surgical accessibility of the portion of the patient's vasculature where the graft is to be placed.

Not all vascular conditions in which it would be desirable to-place a graft can be so treated. Among the particularly troublesome medical conditions in which it is desirable to place a graft is that of an abdominal aortic aneurysm, in which a portion of the patient's aorta, the major artery carrying blood from the heart, has developed a weakened wall such that the weakened portion will tend to expand under the influence of the patient's blood pressure. An aortic aneurysm presents a life threatening risk that the aneurysm may burst causing massive internal bleeding. Treatment of the condition typically has involved deeply invasive abdominal surgery in which the patient's abdominal cavity is opened to reach and expose the aortic aneurysm. While maintaining the patient on an independent life support system, the region of the aneurysm is incised lengthwise to enable insertion of the graft into the aorta to span the weakened region and define a structurally tubular flow path between the remaining healthy portions of the aorta. The graft so positioned then is sutured in place. The graft thus serves as a reinforcing liner for the weakened portion of the aorta. Such surgical procedures have been characterized by a relatively high mortality and morbidity rate. Typically, patients suffering from the condition are elderly and are less able to survive the rigors of major abdominal surgery. Additionally, there is a substantial degree of risk when the abdominal cavity is opened because the confining pressure of other abdominal organs on the aorta is released. In some cases, the abdominal wall in the region of the aneurysm is so weak that upon release of the confining pressure, the aneurysm bursts with resulting immediate massive hemorrhaging.

It would be desirable, therefore, to provide an apparatus, system and technique for placement of a graft, such as, but not limited to, placement in the abdominal aortic region, with a less invasive procedure that presents less risk to the patient. It is among the general objects of the invention to provide such a system.

BRIEF DESCRIPTION OF THE PRIOR ART

Mirich et al., in "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study", *Radiology* (March 1989), describes the use of nylon covered, self expanding metallic stents to repair abdominal aortic aneurysms that were artificially produced in dogs. Mirich et al. describes a graft framework constructed from three self expanding metallic zigzag stents connected in tandem. The two lower stents are covered with nylon. The graft is anchored in position by barbs attached to both ends of the graft. Delivery of the framework is achieved by compressing the nylon covered graft and advancing it through a catheter with a blunt tipped introducer wire. When the nylon covered portion of the graft bridges the aneurysm, the introducer wire is held in place and the catheter slowly withdrawn. This releases the graft assembly and allows the stents to expand until they press against the vessel walls.

In a similar procedure, Lawrence Jr. et al., in "Percutaneous Endovascular Graft: Experimental Evaluation", *Radiology* (May 1987), discloses the use of an expanding stent of the type disclosed in U.S. Pat. No. 4,580,568 (Gianturco) to anchor and support a Dacron graft. The Gianturco stent comprises a wire formed into a closed zigzag configuration by creating an endless series of straight sections joined by bends. The stent is resiliently collapsible into a smaller generally tubular, low profile shape. In its compressed, low profile shape, the straight sections are arranged side-by-side, in close proximity, to facilitate insertion. The stent is resiliently expandable such that the straight sections press against the wall of the artery to maintain it open when the stent is permitted to resiliently expand.

The procedure disclosed by Lawrence Jr. et al. includes the use of a plurality of Gianturco stents in tandem. Dacron tubing is wrapped around the outside of the middle group of the stents, internalizing the stents within the graft. As a result, the lead and trail stents act as securing means, while the internal stents served to open the tubular graft when the device is released from the catheter. As with the procedure disclosed by Mirich et al., a catheter is used to deliver the graft framework to the treatment site.

The use of expanding stents is discussed further by Dobben et al. in "Prosthetic Urethra Dilatation with the Gianturco Self-expanding Metallic Stent: A Feasibility Study in Cadaver Specimens and Dogs", AJR 156:757–761 (April 1991). Dobben et al. describes the use of stainless steel stents bent into a zigzag pattern and then formed into a cylinder. Stents having flared ends as well as stents that are not flared are discussed. The stents are said to have been delivered to a predetermined location by using a coaxial Teflon introducer system. The flared stents were said to have been flared outwardly at both ends, and, when fully expanded, had a smaller diameter in the center than at the ends.

SUMMARY OF THE INVENTION

The present invention relates to a device, system and technique for the minimally invasive, percutaneous placement of a vascular graft, such as in the repair of an abdominal aortic aneurysm. The device comprises an implant which includes a tubular synthetic graft having proximal and distal ends and a resilient, self-expanding anchor of a length at least as long as that of the graft. In one embodiment, the anchor is formed from a single, continuous

wire bent in a zigzag configuration to define a series of elongate wire segments connected by bends. The anchor defines a three-dimensional generally tubular structure having proximal and distal ends. The anchor is compressible to a low profile (small diameter) and can expand resiliently to an enlarged diameter. In a second embodiment, the anchor is formed of a pair of expandable segments, each formed of a single, continuous wire bent in a zigzag configuration. In the second embodiment, the two expandable segments are joined by at least two, substantially straight struts. In each case, the use of a single anchor having a length sufficient to span the length of the graft allows the physician to reposition or remove the graft if, during the graft implantation, it is determined that the graft is not positioned in the desired location or position.

In one aspect of the invention, the ends of the anchor may extend beyond the ends of the graft, and the exposed ends of the anchor may be curved outwardly. The curved ends of the anchor thus are adapted to bear against the wall of the blood vessel at a plurality of points (in the region of the bends) rather than along the full length of the anchor. By so concentrating the points of contact of the anchor with the blood vessel, a more secure attachment of the anchor to the vessel wall is achieved, thereby reducing the risk of the device migrating downstream in the blood vessel.

In another aspect of the invention, the anchor is intended to maintain close contact with the graft along its entire mutual length. By minimizing the extent to which portions of the anchor protrude radially inwardly into the graft, the cross-sectional area of the lumen through the graft is not compromised. This is desirable, for example, should it be necessary to subsequently treat the patient with a catheter that must be passed through the graft. The absence of radially inwardly protruding anchor portions reduces the risk that the subsequently introduced catheter or other vascularly insertable member might become caught on the anchor.

In still another aspect of the invention, the graft may surround the anchor or the anchor may surround the graft. Additionally, embodiments in which some longitudinal elements of the anchor are contained within the graft and other longitudinal elements are positioned on the outside of the graft are contemplated as well.

Although the anchor may be attached to the graft by sutures, in a further aspect of the invention, it is preferred to capture a marginal end portion of the graft within a pair of wires that define a portion of the anchor. The wire portions may be joined in a manner that captures a marginal end portion of the graft without the use of bulky sutures.

Attachment of the anchor to the vessel wall may further be enhanced by one or more radially outwardly protruding hooks attached to the anchor. The hooks engage the vessel wall under the influence of the resilient anchor and enhance the anchor's resistance to migration once the graft is properly positioned. The hooks preferably are formed on the end of short segments of wire that are welded to the anchor to locate the hooks at regions adjacent to the distal bends. The hooks extend a short distance beyond the bends and become engaged in the blood vessel wall once the anchor is expanded.

The graft assembly can be delivered percutaneously with a catheter-like delivery device that includes an outer sheath and an inner positioning member that extends through the outer sheath. The graft assembly is compacted to its low profile configuration and is loaded within the distal end of the sheath. The delivery device then is advanced into the patient's vascular system in an over-the-wire technique. The positioning member has a hollow lumen adapted to receive the guidewire. When the delivery system and graft assembly have been advanced to the intended site of deployment, the positioning member is held stationary while the sheath is withdrawn. As the sheath withdraws, the anchor and graft are progressively exposed so that the anchor can expand and resiliently engage the wall of the blood vessel.

It is among the general objects of the invention to provide a percutaneously deliverable vascular prosthesis that can be repositioned or removed prior to completion of an implantation procedure.

It is another object of the invention to provide an improved percutaneously deliverable vascular prosthesis that avoids post implantation migration.

Another object of the invention is to provide an improved system and technique for more securely anchoring and positioning the vascular graft within a blood vessel.

A further object of the invention is to provide an improved technique for treating a vascular aneurysm.

Another object of the invention is to provide a percutaneously placeable graft assembly that includes a graft and a resiliently expandable anchor attached to the graft in which the anchor is configured to concentrate the expansion force developed by the anchor at a plurality of discrete locations.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying drawings wherein:

FIG. **1** is a side elevation of one embodiment of the implant assembly;

FIG. **2** is a side elevation of an anchor for use with the implant of FIG. **1**;

FIG. **3** is a side elevation of a second embodiment of the implant assembly;

FIG. **4** is a side elevation of an anchor assembly for use with the implant of FIG. **3**;

FIG. **5** is a diagrammatic illustration of the use of sutures to attach an anchor to a graft;

FIG. **6** is an illustration of an anchor segment and attached hook;

FIG. **7** is an illustration of a portion of the anchor as seen from the right of FIG. **6**;

FIG. **8** is an enlarged illustration of the hook arrangement in FIG. **6**;

FIG. **9** is an enlarged illustration of the hook arrangement in FIG. **7**;

FIG. **10** is an illustration of the distal end of a graft having holes adapted to receive and be attached to an anchor;

FIGS. **11** and **12** are illustrations of the manner in which an anchor may be attached to the graft as shown in FIG. **10**;

FIG. **13** is an illustration of the delivery device for the implant assembly;

FIG. **14** is an enlarged sectional illustration of the distal region of the delivery device loaded with the implant assembly and in readiness for insertion into the patient;

FIG. **15** is a diagrammatic illustration of the manner in which the graft assembly may be loaded into the distal end of the delivery device; and

FIGS. **16***a*–**16***c* are diagrammatic illustrations of a section of the delivery device which engages the proximal end of the implant.

FIGS. 17*a*–17*c* are diagrammatic illustrations of the process by which al implant may be recaptured during an implantation procedure.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 illustrates one embodiment of an implant assembly, indicated generally at **10**, adapted for use in the present invention. The assembly **10** includes a synthetic vascular graft **20** and an anchor **30** which are intended to be placed within a patient's blood vessel, the invention being described, for example, in connection with the treatment of an abdominal aneurysm. The graft **20** is tubular and may be formed from materials and in any of a variety of constructions known in the art. For example, the graft may be formed from expanded polytetrafluoroethylene with a porosity and internodal distance similar to grafts presently commercially available. Alternately, the graft may be formed from a fabric material, either woven or knitted, or in other configurations known in the art. Preferably, the graft has a porosity that will exhibit the desired properties of promoting tissue ingrowth while precluding undesired blood leakage. The graft can be provided with one or more radiopaque stripes **11** to facilitate fluoroscopic or X-ray observation of the graft. The stripes may be formed in the graft by any conventional means as will be appreciated by those skilled in the art. The implant assembly **10** also includes an anchor **30** that is secured to the graft and serves to retain the graft in position in the blood vessel. The anchor may be positioned either on the interior or the exterior of the graft.

FIG. **2** shows, somewhat diagrammatically, a first embodiment of the anchor **30**. For clarity, a portion of the anchor has been drawn in phantom. The anchor **30** can be made from a single continuous length of metal wire. The wire preferably may be an alloy of nickel (35%), cobalt (35%), chromium (20%), and molybdenum (10%). Such wire is commonly available from a number of suppliers under the designation MP35N. The alloy has high corrosion resistance, is non-magnetic and has a strength comparable to stainless steel. The wire is formed to define a series of wire segments **34** and alternating proximal and distal bends **36**P, **36**D. The segments **34** and bends **36**P, **36**D are arranged in a zigzag pattern. The wire segments **34** preferably have the same length. In making the anchor a wire, so bent, is attached, as by welding, at its ends to form a three-dimensional, generally tubular structure. In addition, each of the wire segments **34** is connected to the two segments adjacent to either side of it by welds **32**P and **32**D. Thus, between each of the proximal and distal bends, **36**P, **36**D is a pair of welds **32**P, **32**D that join the segment **34** connecting the proximal and distal bends to the segments positioned adjacent to it on either side.

The resulting anchor is resilient and can be compressed to a low profile, small diameter configuration suited for percutaneous delivery into the patient's vascular system. In addition, the provision of the welds to join adjacent wire segments provides the anchor with varying degrees of radial force along its axial length. It is desired that the radial forces be greatest at the axial ends of the implant, with the middle section exhibiting a weaker axial force. That effect can be achieved by joining each segment to its adjacent segments in the manner described. Furthermore, as detailed below, grafts having a single anchor extending along their entire length are adapted for removal during the implantation process if so desired.

In accordance with the invention, if the anchor is of a length such that one or both ends extend beyond the graft, either one or both of the portions of the anchor segments **34** which extend beyond the graft can be curved so as to provide enhanced anchoring capabilities. In that case, the bends **36**P and/or **36**D provide point-to-point contact with the blood vessel wall, thereby enhancing the anchoring by providing localized areas of high contact force.

The security of the engagement between the anchor **30** and the aorta wall may be further enhanced by hooks suggested diagrammatically at **40**, which are secured to the anchor **30**. The hooks **40**, as suggested in FIG. **2**, are formed on the distal ends of hook wire segments **42**. The hook wire segments **42** preferably are formed from the same material as the main wire of the anchor **30**. They are secured along the anchor segments **34**, such that the hooks **40** are disposed beyond the distal bends **36**D. The segments **42** are welded to the anchor segment **34** at first (proximal) and second (distal) junctions **46**, **48**. The hooks **40** preferably are sharp and aid in attaching the anchor **30** to the aorta wall to prevent migration after the device is implanted. It should be understood that although FIG. **1** illustrates a hook associated with each of the anchor segments **34**, it may not be necessary to include a hook for each anchor segment. The curved configuration of the anchor segments serves several purposes It results in a decrease in the surface area along which the anchor **30** engages the vessel wall. That, in turn, concentrates the resilient expansion force of the anchor at the point-like regions of contact of the bends **36**P, **36**D and hooks **40** so that they will tend to more firmly dig into and bear against the vessel wall. The anchor segment **34** may be curved to include an arc of between about 5° to about 30°.

A second embodiment of the graft assembly is shown in FIGS. **3** and **4**. In that embodiment, the graft **20** is of the same construction as described above. The anchor **30'**, however, is formed of a pair of expandable segments **33**, **35** each joined by at least two longitudinal struts **34'**. Each of the expandable segments **33**, **35** is formed of a single continuous segment of wire having a series of zigzag bends **37**. The struts **34'** extend between the expandable segments **33**, **35**, being welded between the proximal end of one segment **33** and the distal end of the other segment **35**. The anchor **30'** may be positioned on either the inside or the outside of the graft **20**. Additionally, in one embodiment, the anchor may be mounted such that some struts are positioned on the inside of the graft while other struts are positioned on the outside of the graft.

As with the previously described embodiment, the anchor **30'** may be of a length such that one or both ends extend beyond the graft. Additionally, one or both of the segments, if extending beyond the graft, may be curved to assist in maintaining the graft in position in a blood vessel. Also, hooks extending from the anchor may be used to further aid in maintaining the position of the implant. Finally, as in the earlier embodiment, the use of an anchor extending along the entire length of the implant allows the implant to be removed during the implantation procedure if desired.

Either anchor **30**, **30'** may be secured to the graft **20** by sutures. In the case of the first embodiment anchor **30**, the suture preferably secures the anchors at the welds **32**D, **32**P. In the case of the second embodiment anchor **30'**, the suture preferably secures the anchor at the proximal bends of the distal anchor segment **33** and at the distal ends of proximal anchor segment **35**. As shown in FIG. **5**, anchor **30'** may be secured to the graft by suturing the bends of segment **35** of anchor **30'** to the graft **20**. The suture **50** is passed through the mesh of the graft **20** and around a portion of the anchor. Preferably, the suture **50** is passed about the securing section of the anchor four times, with each successive stitch **51**, **52**, **53**, **54** being further removed from the bend.

FIGS. **6** and **7** illustrate, in more representative detail the configuration of a segment **34** of an anchor in accordance with the invention. The segment **34** of FIG. **6** is curved in the manner described above, however such curvature is optional. In the curved configuration, the wire segments **42** that support the hooks **40** extend more fully toward the proximal bend **36**P than in the configurations illustrated in FIGS. **2** and **4**, respectively.

By way of dimensional example, in an anchor adapted for use in an abdominal aortic aneurysm repair prosthesis as illustrated in FIGS. **1** and **2**, the hook wire segment **42** on which the hook **40** is formed may be of the order of ⅞ of an inch long with the hook **40** being disposed approximately ⅛ of an inch above the distal bend **34**D associated with that hook. The wire from which the anchor and the hook segment are made may be of the order of 0.014 inches diameter. The proximal and distal resistance welds by which the hook segment is secured to the anchor segment may be disposed, respectively, about ⅝ of an inch and about ¼ of an inch from the distal bend **36**D. FIG. **6** illustrates a representative degree of optional curvature for the wire segment and an associated hook segment. By way of example, the degree of curvature may be of the order of **3** inches in radius. The relaxed expanded diameter of the anchor **30** may be between about 10 mm to 40 mm, depending on the blood vessel into which it is to be placed.

FIGS. **8** and **9** illustrate in enlarged detail the configuration of a typical hook **40** and its associated bend. Again, for purposes of illustration the anchor **30** of FIGS. **1** and **2** has been shown. The hook is provided with a sharpened tip **50** formed at the end of a generally radially outwardly protruding portion **52**. The protruding portion which may be of the order of 0.050 inches long and may be formed by bending the hook wire **42** from which the hook is formed about a pin of the order of 0.050 inches in diameter. The bends **36**P, **36**D may be formed by bending the wire about a pin of the order of 0.100 inches in diameter.

FIGS. **10**, **11** and **12** illustrate portions of an assembly incorporating the hook configuration of FIGS. **6**–**9** and an improved arrangement for attaching the graft **20** to the anchor **30**' of FIG. **4**. As shown in FIG. **10**, the distal end of the graft **20** is formed to include a plurality of circumferentially spaced holes **54** disposed slightly proximally of the distal edge **56** of the graft. All edges of the graft including the distal edge **56** as well as the edges defined by the holes may be heat sealed or otherwise treated, if necessary, to prevent unraveling of the graft. By way of example, for an anchor **30**' configured as described above (FIG. **4**), the holes **54** may be of the order of 0.016 inches diameter and may be spaced approximately 2 mm from the distal edge **56** of the graft. FIGS. **11** and **12** illustrate the manner in which the anchor is joined to the graft. After the anchor **30**' is formed as described above, the hook segment **42** is joined to the anchor, such as by resistance welding, but only at one of the junctures **46**, **48**, and preferably, at the proximal juncture **46**. When the desired number of hook segments **42** have been attached to the anchor segment **33**, the anchor is inserted into the the graft **20** and positioned to allow a portion of each hook segment **42** to extend out of the graft through the holes **54** The position of the anchor **30**' is adjusted until the distal, unattached portion of each hook wire segment **42** overlies the outside of the distal margin of the graft while its proximal end **58** and proximal juncture **46** are positioned on the graft interior just proximally to the holes **54**. With the graft and anchor so assembled, the distal juncture **48** can be made using a weld or the like. Thus, the marginal portion of the graft is captured between the generally parallel anchor segments **34** and associated hook segments **42** between the proximal and distal junctures **46**, **48**. This arrangement is preferred to a sutured connection between the anchor and graft in that it cannot become unraveled and, additionally, is less bulky than the sutured connection.

In the preferred embodiment of the invention, the implant is selected so that when fully expanded, it will match or be slightly larger in diameter than the vessel to which it is to be implanted. It is intended that when the implant is deployed and expanded, the ends of the graft will lie as close to the surface of the lumen of the blood vessel as possible in order to enhance tissue ingrowth into the graft wall and provide a smooth transition in the surface (that defines the flow area from the healthy portion of the blood vessel into the graft. To that end, the anchor should be selected with respect to the graft so that the relaxed, freely expanded anchor will define a diameter greater than the fully expanded diameter of the graft. That assures that when the device is deployed, the anchor will open the end of the graft fully.

FIGS. **13**–**16** illustrate the catheter-like device by which the implant assembly may be percutaneously inserted and deployed within the patient's blood vessel. The delivery device includes an elongate flexible sheath **60** formed from a suitable polymeric material and having a fitting **62**, including a Tuohy-Borst adapter **64** at its proximal end. The sheath **60** is adapted to receive a positioning tube **66** that has, at its distal tip, a flexible distally tapered dilator **68** and a stay **78** located proximally of the dilator tip. The proximal end **72** of the dilator tip is dimensioned to be received within the lumen at the distal end of the flexible sheath. The positioning tube **66** is longer than the sheath **60** so that when assembled, the proximal end of the tube **66** will protrude proximally of the Tuohy-Borst sheath adaptor **64**. The positioning tube **66** is adapted to receive a guidewire **88** to facilitate placement of the device. The device may also be provided with a side arm **63**. The side arm provides a channel through which a fluid, such as a radiopaque dye, may be injected into the patient to aid in fluoroscopic visualization during the implantation procedure.

When the delivery device and graft assembly are arranged in readiness for insertion into the patient, the graft assembly will be contained within the distal end of the sheath **60** and about a portion of the positioning tube as illustrated in enlarged detail in FIG. **14**. As suggested diagrammatically in FIG. **15**, the graft assembly is loaded into the delivery device using a funnel-like loader **70** having an enlarged distal inlet end **72** and a narrowed proximal outlet end **74**.

FIG. **15**, which is diagrammatic and not to scale, illustrates the configuration of the delivery device when loading the graft assembly. The positioning tube **66** is extended through the sheath with its distal end extending beyond the distal tip of the sheath so that a stay **78** is spaced a short distance from the distal end of the sheath **60**. The funnel **70** is disposed about the positioning tube **66** with the proximal end of the funnel being in communication with the distal outlet end of the sheath. The graft assembly is placed over the distal end of the positioning tube **66** in a position such that the proximal bends of anchor segment **35** are disposed against the stay **78**. The graft assembly then is pushed into the funnel to compress the proximal end of the anchor, and move the anchor, stay, and positioning tube into the lumen **80** at the distal end of the sheath. As the positioning tube and graft assembly are pushed through the funnel **70**, the graft is progressively constricted to a low profile about the positioning tube. Consequently, as the graft assembly constricts about the positioning tube **66** both are advanced into the distal end of the sheath, with the anchor compressed to a low profile with its proximal bends bearing against the distal face of the stay **78**.

As shown in FIGS. **16***a*–**16***c*, the stay **78** which is used to maintain the position of the implant **10** as the sheath **60** is withdrawn operates in conjunction with an implant retention device **85**. The retention device **85** takes the form of a plurality of radially extending spokes **81** attached to a central hub **83**. The retention device **85** may be mounted on the positioning tube **66** a short distance distally to the stay **78**, or it may be formed as an integral part of the stay. As can be seen most clearly in FIG. **16***a*, in extending radially, the spokes **81** of the retention device **85** engage the proximal-most ends of the anchor **30**, **30'** when the proximal portion of the anchor is compressed within the sheath **60**. The engagement is achieved by a distal portion of each spoke which becomes seated in the space on the interior of the bends at the proximal end of the anchor. The result is that the anchor, (and thus, the entire implant), is prevented from moving distally relative to the stay. In so doing, if removal or repositioning of the implant is desired, the sheath **60** may be advanced distally to recapture the implant assembly. Since the proximal-most bends of the implant assembly are retained by the radial spokes **81**, the implant is prevented from moving in the distal direction as the sheath is advanced.

Once the implant has been positioned in its final location, the sheath is fully withdrawn, thereby allowing the proximal-most section of the anchor to expand outwardly into contact with the blood vessel wall. Upon expansion, the proximal portion of the anchor is released from the retention assembly **85**, as the anchor expands radially beyond the ends of the spokes. In so doing, the implant assembly is released from the delivery device and deployed within the blood vessel.

The tube **66** preferably is provided with a marker **82** (FIG. **13**) near its proximal end, the marker being located so that when it is exposed proximally of the fitting **62**, the graft assembly will have been withdrawn fully into the distal end of the sheath and the proximal end of the dilator tip also is drawn slightly into the distal tip of the sheath, as shown in FIG. **14**. The distal tip of the sheath preferably is provided with an inner lining segment **84** formed from a relatively hard material. The lining segment is dimensioned and located to be aligned with the hooks on the distal end of the distal anchor and serves to prevent the hooks **40** from digging into the softer material from which the sheath is formed. Additionally, the distal liner preferably is formed from a material sufficiently dense to be observed under fluoroscopy. When the device is thus loaded, it is in readinesds for insertion into the patient and deployment of the graft assembly.

The device can be inserted percutaneously into the patient's vasculature with the aid of a guidewire. The guidewire **88** may be preliminarily loaded into the lumen of the positioning tube before the delivery device is inserted into the patient or, alternately, the guidewire may be placed separately in a preliminary procedure into the patient's blood vessel. In either case, the delivery device is advanced into the patient's blood vessel, for example, as through the femoral artery when placing a graft assembly to treat an abdominal aneurysm. The guidewire may be advanced independently toward and through the region to be treated. The delivery assembly then may be advanced over the guidewire until the graft assembly is in its intended position. In the case of an abdominal aortic aneurysm, the device would be located so that the distal anchor is located distally of the region of the aneurysm such that the graft, when deployed, can pass through the aneurysm thereby lining the artery. With the delivery device so placed, the position of the positioning tube is maintained while the sheath is withdrawn in a proximal direction. The stationary stay maintains engagement with the proximal end of the anchor in the manner described above, thereby preventing proximal movement of the graft assembly while the sheath is withdrawn. As the sheath is progressively withdrawn and the anchor emerges from the distal end of the sheath, the anchor expands into engagement with the inner luminal surface of the blood vessel while simultaneously expanding the distal end of the graft.

The implants are characterized in their ability to be removed or repositioned from the patient prior to completion of the deployment process. In particular, as long as a portion of the implant is maintained within the sheath, the deployment process can be reversed to recapture the implant within the sheath and reposition or remove it. As discussed above, progressive withdrawal of the sheath exposes progressive lengths of the implant which expand into contact with the blood vessel walls. During this procedure, fluoroscopic visualization methods can be used to determine if the implant is being positioned as desired.

If the positioning is as desired, the sheath is withdrawn along the entire length of the implant, thereby releasing the implant and allowing it to expand into contact with the blood vessel along the entire length of the implant. However, if it is determined prior to complete withdrawal of the sheath (and concurrent release of the implant) that the implant is not positioned exactly as desired, the sheath can be advanced distally to recapture the implant. Since, in each embodiment, the implant includes a single anchor assembly along the entire length of the graft, compression of the proximal end of the graft, such as by advancing the sheath, allows the compression force to be communicated distally. As a result, the sheath may be advanced over the entire implant assembly, progressively collapsing and recapturing the implant.

In contrast, implants having a distal anchor and, optionally, a separate proximal anchor, cannot be recaptured following release of the distal anchor from a sheath since there is no mechanism for holding and recompressing (i.e., recapturing) that anchor. Furthermore, even if one were to use fluoroscopic visualization methods to determine the positioning of the implant prior to complete release of the distal anchor, it is unlikely that satisfactory results could be achieved since an insufficient amount of the implant would be exposed to determine its ultimate location and position.

FIGS. **17***a*–**17***c* depict the implant removal process described above. In FIG. **17***a*, an implant **10** having either an anchor **30** of the embodiment shown in FIG. **2** or anchor **30'** of the embodiment shown in FIG. **4** is partially released from the delivery sheath **60**. The distal end of the implant has deployed and seated against the wall of the blood vessel **100**. If at this point it is determined, such as by fluoroscopic visualization, that repositioning or removal of the implant is required, the sheath can be advanced distally to progressively recapture the implant. As shown in FIG. **17***b*, the sheath **60** has been advanced in the distal direction D causing compression and recapture of a portion of the implant **10**. The compression forces on the proximal end of the implant are transferred to its distal end, causing the distal end to begin contracting as well. In FIG. **17***c*, the sheath has been advanced over the entire length of the implant. In so doing, the implant has been removed from contact with the vessel wall and can be removed from the patient or positioned at a different location.

It should also be appreciated that the scope of the invention is not confined to the specific embodiments illustrated

and described herein. Rather, it is the intention of the applicant that the scope of the invention be determined by the appended claims and their equivalents.

We claim:

1. A method for repairing a blood vessel comprising the steps of:

a) providing an implant which comprises:

a graft having a proximal end, a distal end, and an axial length; and

an anchor having a proximal end, a distal end and an axial length at least equal to that of the graft, the anchor extending along the full length of the graft and supporting the graft, wherein at least the proximal end and the distal end of the anchor are resiliently expandable and connected to each other by at least two longitudinal segments, each of the segments extending between the proximal and distal ends of the anchor and further being constructed and arranged to transmit a radial compression force from one end of the anchor to the other

b) positioning the implant at a desired location within the blood vessel, and

c) securing the implant within the blood vessel such that migration of the implant is prevented.

2. A method as in claim 1 wherein the implant is secured across an aneurysm.

* * * * *

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United States Patent [19]

Mayer

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[45] Date of Patent: Oct. 20, 1998

[54] **CLAD COMPOSITE STENT**

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[73] Assignee: **Schneider (USA) Inc**, Plymouth, Minn.

[21] Appl. No.: **469,810**

[22] Filed: **Jun. 6, 1995**

Related U.S. Application Data

[63] Continuation of Ser. No. 6,216, Jan. 19, 1993, abandoned.

[51] **Int. Cl.**[6] **A61F 2/02**; A61F 2/06

[52] **U.S. Cl.** **623/11**; 623/1; 606/198

[58] **Field of Search** 623/1, 11, 12; 606/194, 191, 192, 193, 195–200; 428/364, 375, 378, 379, 386, 389, 397

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Attorney, Agent, or Firm—Peter C. Richardson; Lawrence C. Akers; Philip C. Strassburger

[57] **ABSTRACT**

A body compatible stent is formed of multiple filaments arranged in two sets of oppositely directed helical windings interwoven with one another in a braided configuration. Each of the filaments is a composite including a central core and a case surrounding the core. In the more preferred version, the core is formed of a radiopaque and relatively ductile material, e.g. tantalum or platinum. The outer case is formed of a relatively resilient material, e.g. a cobalt/chromium based alloy. Favorable mechanical characteristics of the stent are determined by the case, while the core enables in vivo imaging of the stent. The composite filaments are formed by a drawn filled tubing process in which the core is inserted into a tubular case of a diameter substantially more than the intended final filament diameter. The composite filament is cold-worked in several steps to reduce its diameter, and annealed between successive cold-working steps. After the final cold working step, the composite filament is formed into the desired shape and age hardened. Alternative composite filaments employ an intermediate barrier layer between the case and core, a biocompatible cover layer surrounding the case, and a radiopaque case surrounding a structural core.

15 Claims, 2 Drawing Sheets

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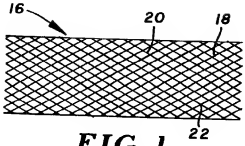


FIG. 1

FIG. 2

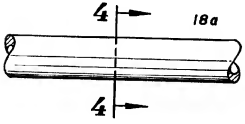


FIG. 3

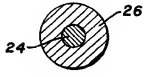


FIG. 4

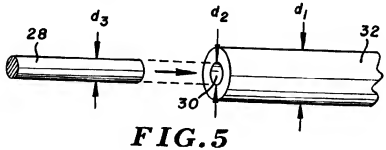


FIG. 5

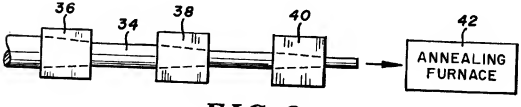


FIG. 6

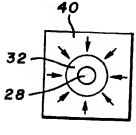


FIG. 7

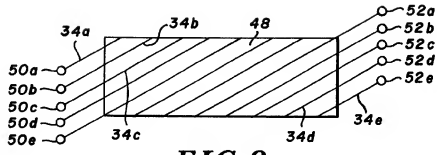


FIG.8

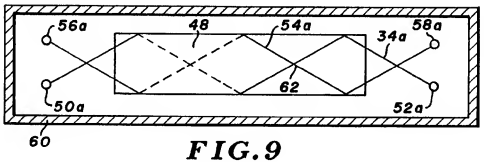
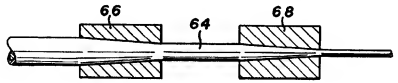


FIG.9

FIG.10



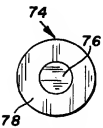


FIG.11

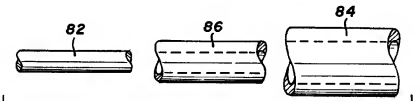


FIG.12

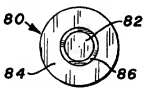


FIG.13

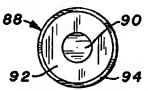


FIG.14

CLAD COMPOSITE STENT

This is a continuation of parent application Ser. No. 08/006,216, filed Jan. 19, 1993, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to body implantable medical devices, and more particularly to stents and other prostheses configured for high radio-opacity as well as favorable mechanical characteristics.

Recently several prostheses, typically of lattice work or open frame construction, have been developed for a variety of medical applications, e.g. intravascular stents for treating stenosis, prostheses for maintaining openings in the urinary tracts, biliary prostheses, esophageal stents, renal stents, and vena cava filters to counter thrombosis. One particularly well accepted device is a self-expanding mesh stent disclosed in U.S. Pat. No. 4,655,771 (Wallsten). The stent is a flexible tubular braided structure formed of helically wound thread elements. The thread elements can be constructed of a biocompatible plastic or metal, e.g. certain stainless steels, polypropylene, polyesters and polyurethanes.

Alternatively, stents and other prostheses can be expandable by plastic deformation, usually by expanding a dilation balloon surrounded by the prosthesis. For example, U.S. Pat. No. 4,733,665 (Palmaz) discloses an intraluminal graft constructed of stainless steel strands, either woven or welded at their intersections with silver. U.S. Pat. No. 4,886,062 (Wiktor) features a balloon expandable stent constructed of stainless steel, a copper alloy, titanium, or gold.

Regardless of whether the prosthesis is self-expanding or plastically expanded, accurate placement of the prosthesis is critical to its effective performance. Accordingly, there is a need to visually perceive the prosthesis as it is being placed within a blood vessel or other body cavity. Further, it is advantageous and sometimes necessary to visually locate and inspect a previously deployed prosthesis.

Fluoroscopy is the prevailing technique for such visualization, and it requires radio-opacity in the materials to be imaged. The preferred structural materials for prosthesis construction, e.g. stainless steels and cobalt-based alloys, are not highly radiopaque. Consequently, prostheses constructed of these materials do not lend themselves well to fluoroscopic imaging.

Several techniques have been proposed, in apparent recognition of this difficulty. For example, U.S. Pat. No. 4,681,110 (Wiktor) discloses a self-expanding blood vessel liner formed of woven plastic strands, radially compressed for delivery within a tube. A metal ring around the tube is radiopaque. Similarly, U.S. Pat. No. 4,830,003 (Wolff) discusses confining a radially self-expanding stent within a delivery tube, and providing radiopaque markers on the delivery tube. This approach facilitates imaging only during deployment and initial placement.

To permit fluoroscopic imaging after placement, the stent itself must be radiopaque. The Wolff patent suggests that the stent can be formed of platinum or a platinum-iridium alloy for substantially greater radio-opacity. Such stent, however, lacks the required elasticity, and would exhibit poor resistance to fatigue. The Wiktor '110 patent teaches the attachment of metal staples to its blood vessel liner, to enhance radio-opacity. However, for many applications (e.g. in blood vessels), the stent is so small that such staples either would be too small to provide useful fluoroscopic imaging, or would adversely affect the efficiency and safety of deploying the stent or other prosthesis. This Wiktor patent also suggests infusing its plastic strands with a suitable filler, e.g. gold or barium sulfate, to enhance radio-opacity. Wiktor provides no teaching as to how this might be done. Further, given the small size of prostheses intended for blood vessel placement, this technique is unlikely to materially enhance radio-opacity, due to an insufficient amount and density of the gold or barium sulfate.

Therefore, it is an object of the present invention to provide a stent or other prosthesis with substantially enhanced radio-opacity, without any substantial reduction in the favorable mechanical properties of the prosthesis.

Another object is to provide a resilient body insertable composite filament having a high degree of radio-opacity and favorable structural characteristics, even for stents employing relatively small diameter filaments.

A further object is to provide a process for manufacturing a composite filament consisting essentially of a structural material for imparting desired mechanical characteristics, in combination with a radiopaque material to substantially enhance fluoroscopic imaging of the filament.

Yet another object is to provide a case composite prosthesis in which a highly radiopaque material and a structural material cooperate to provide mechanical stability and enhanced fluoroscopic imaging, and further are selectively matched for compatibility as to their crystalline structure, coefficients of thermal expansion, and annealing temperatures.

SUMMARY OF THE INVENTION

To achieve these and other objects, there is provided a process for manufacturing a resilient body insertable composite filament. The process includes the following steps:

a. providing an elongate cylindrical core substantially uniform in lateral cross-section and having a core diameter, and an elongate tubular case or shell substantially uniform in lateral cross-section and having a case inside diameter, wherein one of the core and case is formed of a radiopaque material and the other is formed of a resilient material having an yield strength (0.2% offset) of at least 150,000 psi, wherein the core diameter is less than the interior diameter of the case, and the lateral cross-sectional area of the core and case is at most ten times the lateral cross-sectional area of the core;

b. inserting the core into the case to form an elongate composite filament in which the case surrounds the core;

c. cold-working the composite filament to reduce the lateral cross-sectional area of the composite filament by at least 15%, whereby the composite filament has a selected diameter less than an initial outside diameter of composite filament before cold-working;

d. annealing the composite filament after cold-working, to substantially remove strain hardening and other stresses induced by the cold-working step;

e. mechanically forming the annealed composite filament into a predetermined shape; and

f. after the cold-working and annealing steps, and while maintaining the composite filament in the predetermined shape, age hardening the composite filament.

In one preferred version of the process, the radiopaque material has a linear attenuation coefficient, at 100 KeV, of at least 25 cm^{-1}. The radiopaque material forms the core, and is at least as ductile as the case. The outside diameter of

the composite filament, before cold-working, preferably is at most about six millimeters (about 0.25 inches). The cold-working step can include drawing the composite filament serially through several dies, with each die plastically deforming the composite filament to reduce the outside diameter. Whenever a stage including one or more cold-working dies has reduced the cross-sectional area by at least 25%, an annealing step should be performed before any further cold-working.

During each annealing step, the composite filament is heated to a temperature in the range of about 1900°–2300° F. for a period depending on the filament diameter, typically in the range of several seconds to several minutes. The core material and cladding (case) materials preferably are selected to have overlapping annealing temperature ranges, and similar coefficients of thermal expansion. The core and case materials further can be selectively matched as to their crystalline structure and metallurgical compatibility.

In an alternative version of the process, the initial outside diameter of the composite structure (billet) typically is at least fifty millimeters (about two inches) in diameter. Then, before cold-working, the composite filament is subjected to temperatures in the annealing range while the outside diameter is substantially reduced, either by swaging or by pulltrusion, in successive increments until the outside diameter is at most about 6 millimeters (0.25 inches). The resulting filament is processed as before, in alternative cold-working and annealing stages.

Further according to the process, the composite filament can be severed into a plurality of strands. Then, the strands are arranged in two oppositely directed sets of parallel helical windings about a cylindrical form, with the strands intertwined in a braided configuration to form multiple intersections. Then, while the strands are maintained in a predetermined uniform tension, they are heated to a temperature in the range of about 700°–1200° F., more preferably 900°–1000° F., for a time sufficient to age harden the helical windings.

The result of this process is a resilient, body implantable prosthesis. The prosthesis has a plurality of resilient strands, helically wound in two oppositely directed sets of spaced apart and parallel strands, interwoven with one another in a braided configuration. Each of the strands includes an elongate core and an elongate tubular case surrounding the core. A cross-sectional area of the core is at least ten percent of the cross-sectional area of the strand. The core is constructed of a first material having a linear attenuation coefficient of at least 25 cm^{-1} at 100 KeV. The case is constructed of a resilient second material, less ductile than the first material.

More generally, the process can be employed to form a body compatible device comprising an elongate filament substantially uniform in lateral cross-section over its length and including an elongate cylindrical core and an elongate tubular case surrounding the core. One of the core and case is constructed of a first material having an yield strength (0.2% offset) of at least twice that of the second material. The other of the core and case is constructed of a second material being radiopaque and at least as ductile as the first material.

In a highly preferred version of the invention, the core is constructed of tantalum for radio-opacity, and the case is constructed of a cobalt-based alloy, e.g. as available under the brand names "Elgiloy", "Phynox" and "MP35N". The "Elgiloy" and "Phynox" alloys contain cobalt, chromium, nickel, and molybdenum, along with iron. Either of these alloys is well matched with tantalum, in terms of overlapping annealing temperature ranges, coefficients of thermal expansion and crystalline structure. The tantalum core and alloy case can be contiguous with one another, with virtually no formation of intermetallics.

When otherwise compatible core and case materials present the risk of intermetallic formation, an intermediate layer, e.g. of tantalum, niobium, or platinum, can be formed between the core and the case to provide a barrier against intermetallic formation. Further, if the case itself is not sufficiently biocompatible, a biocompatible coating or film can surround the case. Tantalum, platinum, iridium and their alloys, or stainless steels can be used for this purpose.

While disclosed herein in connection with a radially self-expanding stent, the composite filaments can be employed in constructing other implantable medical devices, e.g. vena cava filters, blood filters and thrombosis coils. Thus, in accordance with the present invention there is provided a resilient, body compatible prosthesis which, despite being sufficiently small for placement within blood vessels and similarly sized body cavities, has sufficient radio-opacity for fluoroscopic imaging based on the prosthesis materials themselves.

IN THE DRAWINGS

For a further understanding of the above and other features and advantages, reference is made to the following detailed description and to the drawings, in which:

FIG. **1** is a side elevation of a self-expanding stent constructed according to the present invention;

FIG. **2** is an end elevational view of the stent;

FIG. **3** is an enlarged partial view of one of the composite filaments forming the stent;

FIG. **4** is an enlarged sectional view taken along the line **4**—**4** in FIG. **3**;

FIGS. **5**–**9** schematically illustrate a process for manufacturing the stent;

FIG. **10** schematically illustrates a swaging step of an alternative process for manufacturing the stent;

FIG. **11** is an end elevational view of an alternative embodiment filament;

FIG. **12** is an elevational view of several components of an alternative composite filament constructed according to the present invention;

FIG. **13** is an end elevational view of the composite filament formed by the components shown in FIG. **12**; and

FIG. **14** is an end elevational view of another alternative embodiment composite filament.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Turning now to the drawings, there is shown in FIGS. **1** and **2** a body implantable prosthesis **16**, frequently referred to as a stent. Stent **16** is of open mesh or weave construction, consisting of two sets of oppositely directed, parallel and spaced apart helically wound strands or filaments indicated at **18** and **20**, respectively. The sets of strands are interwoven in an over and under braided configuration to form multiple intersections, one of which is indicated at **22**.

Stent **16** is illustrated in its relaxed state, i.e. in the configuration it assumes when subject to no external stresses. The filaments or strands of stent **16** are resilient, permitting a radial compression of the stent into a reduced-radius, extended-length configuration suitable for transluminal delivery of the stent to the intended placement site. As a typical example, stent **16** can have a diameter of about ten

millimeters in the relaxed state, and is elastically compressed to a diameter of about 2 millimeters (0.08 inches) and an axial length of about twice the axial length of the relaxed stent. However, different applications call for different diameters. Further, it is well known to predetermine the degree of axial elongation for a given radial compression, by selectively controlling the angle between the oppositely directed helical strands.

Inelastic open-weave prostheses, expandable for example by dilation balloons, provide an alternative to resilient prostheses. Resilient or self-expanding prostheses often are preferred, as they can be deployed without dilation balloons or other stent expanding means. Self-expanding stents can be preselected according to the diameter of the blood vessel or other intended fixation site. While their deployment requires skill in stent positioning, such deployment does not require the additional skill of carefully dilating the balloon to plastically expand the prosthesis to the appropriate diameter. Further, the self-expanding stent remains at least slightly elastically compressed after fixation, and thus has a restoring force which facilitates acute fixation. By contrast, a plastically expanded stent must rely on the restoring force of deformed tissue, or on hooks, barbs, or other independent fixation elements.

Accordingly, materials forming the strands for filaments must be strong and resilient, biocompatible, and resistant to fatigue and corrosion. Vascular applications require hemocompatibility as well. Several materials meet these needs, including stainless "spring" steels, and certain cobalt-based alloys: more particularly two alloys including cobalt, chromium, iron, nickel and molybdenum sold under the brand names "Elgiloy" (available from Carpenter Technology Corporation of Reading, Pa.) and "Phynox" (available from Metal Imphy of Imphy, France), respectively. Another suitable cobalt-chromium alloy is available under the brand name "MP35N" from Carpenter Technology Corporation of Reading, Pa.

Further, it is advantageous to form a prosthesis with substantial open space to promote embedding of the stent into tissue, and fibrotic growth through the stent wall to enhance long-term fixation. A more open construction also enables substantial radial compression of the prosthesis for deployment. In a typical construction suitable for transluminal implantation, the filaments can have a diameter of about 0.1 millimeter (0.004 inches), with adjacent parallel filaments spaced apart from one another by about 1–2 millimeters (0.04–0.08 inches) when the stent is in the relaxed state.

Fluoroscopic imaging of a conventional open weave prosthesis is extremely difficult. Due to their minute diameters and the materials involved, the filaments exhibit a relatively poor contrast to body tissue for fluoroscopic imaging purposes. The filaments also require a high degree of spatial resolution in the imaging equipment involved. Thus, a stent recognizable on X-ray film may not be distinguishable for real time imaging, due to the relatively poor spatial resolution of the video monitor as compared to X-ray film.

According to the present invention, however, prosthesis **16** is substantially more amenable to fluoroscopic imaging, due to the construction of strands **18** and **20**. In particular, the strands cooperate to present a sufficiently radiopaque mass at the tangents of device **16** (parallel to the X-rays) for satisfactory real time imaging. As seen in FIGS. **3** and **4**, a filament **18***a* of the prosthesis is of composite construction, with a radiopaque core **24** surrounded by and concentric with an annular resilient case **26**. Core **24** is highly absorptive of X-rays, preferably having a linear attenuation coefficient of at least 25 (and more preferably at least 50) cm^{-1} at 100 KeV. Materials with relatively high atomic numbers and densities tend to have the necessary attenuation coefficients. More particularly, it has been found that materials with an atomic number (elements) or "effective" atomic number (based on a weighted average of elements in alloys or compounds) of at least fifty, and densities of at least 0.5 pounds per cubic inch, exhibit the required ability to absorb X-rays. Finally, core **24** is preferably a ductile material so that it readily conforms to the shape of the case.

By contrast, case **26** is formed of a highly resilient material, preferably with a yield strength (0.2% offset) of at least 150,000 psi. More preferably, the yield strength is at least 300,000 psi. Consequently, the mechanical behavior of composite filament **18***a* in terms of elastic deformation in response to external stresses is, essentially, the behavior of case **26**.

In addition to individual characteristics of the core and case, it is desirable to selectively match core and case materials based on certain common characteristics. The core and case materials should have the same or substantially the same linear coefficients of thermal expansion. Similarity of core and case materials in their crystalline structure is also an advantage. Finally, the core and case materials should have an overlap in their annealing temperature ranges, to facilitate manufacture of the filaments according to the process to be explained.

In a highly preferred embodiment, core **24** is formed of tantalum, and case **26** is formed of a cobalt-based alloy, more particularly Elgiloy (brand) alloy. Tantalum is a ductile metal having an atomic number of 73 and a density of about 0.6 pounds per cubic inch. Its linear attenuation coefficient, at 100 KeV, is 69.7 cm^{-1}.

The Elgiloy alloy includes principally cobalt and chromium, and has an effective atomic number of less than thirty and a density substantially less than 0.5 pounds per cubic inch. However, the alloy is body compatible, hemocompatible and highly resilient, with a yield strength (0.2% offset) of at least 350,000 psi, after cold-working and age hardening.

Case **26** and core **24** thus cooperate to provide a prosthesis that can be viewed in vivo, and in real time. Of course, the amount of core material in relation to the amount of case material must be sufficient to insure radio-opacity while maintaining the favorable mechanical characteristics of stent **16**. It has been found that the area of core **24**, taken along a transverse or lateral plane as illustrated in FIG. **4**, should be within the range of about ten percent to forty-six percent of the filament lateral cross-sectional area, i.e. the area of the combined case and core.

Tantalum and the Elgiloy alloy are well matched, in that the materials have similar linear coefficients of thermal expansion (3.6×10^{-6} per degree F. and 8.4×10^{-6} per degree F., respectively), similar crystalline structures, and annealing temperatures in the range of 1900°–2300° F. Further, there is virtually no tendency for the formation of intermetallic compounds along the tantalum/Elgiloy alloy interface.

Platinum and platinum alloys (e.g. platinum iridium) also are suitable as materials for core **24**. The atomic number of platinum is 78, and its density is 0.775 pounds per cubic inch. Its linear attenuation coefficient at 100 KeV is 105 cm^{-1}. The linear coefficient of thermal expansion for platinum is about 4.9×10^{-6} per degree F.

Thus, as compared to tantalum, platinum is structurally more compatible with the Elgiloy alloy, and more effectively

absorbs X-rays. Accordingly, platinum is particularly well suited for use in prostheses formed of small diameter filaments. The primary disadvantage of platinum, with respect to tantalum, is its higher cost.

Further materials suitable for radiopaque core **24** include gold, tungsten, iridium, rhenium, ruthenium, and depleted uranium.

Other materials suitable for case **26** include other cobalt-based alloys, e.g. the Phyzox and MP35N brand alloys. Cobalt-chromium and cobalt-chromium-molybdenum orthopedic type alloys also can be employed, as well as alloys of titanium-aluminum-vanadium. The MP35N alloy is widely available, and has a potential for better fatigue strength due to improved manufacturing techniques, particularly as to the vacuum melting process. The titanium-aluminum-vanadium alloys are highly biocompatible, and have more moderate stress/strain responses, i.e. lower elastic moduli.

Composite filaments such as filament **18**a are manufactured by a drawn filled tubing (DFT) process illustrated schematically in FIGS. **7–9**. The DFT process can be performed, for example, by Fort Wayne Metals Research Products Corporation of Ft. Wayne, Ind. The process begins with insertion of a solid cylinder or wire **28** of the core material into a central opening **30** of a tube **32** of the case material. Core wire **28** and tubing **32** are substantially uniform in transverse or lateral sections, i.e. sections taken perpendicular to the longitudinal or axial dimension. For example, tube **32** can have an outer diameter d1 of about 0.102 inch (2.6 mm) and an inner diameter d2 (diameter of opening **30**) of about 0.056 inches (1.42 mm). Core or wire **28** has an outer diameter d3 slightly less than the tube inner diameter, e.g. 0.046 inches (1.17 mm). In general, the wire outer diameter is sufficiently close to the tubing inner diameter to insure that core or wire **28**, upon being inserted into opening **30**, is substantially radially centered within the tubing. At the same time, the interior tubing diameter must exceed the core outside diameter sufficiently to facilitate insertion of the wire into an extended length of wire and tubing, e.g. at least twenty feet.

The values of the tubing inner diameter and the core outer diameter vary with the materials involved. For example, platinum as compared to tantalum has a smoother exterior finish when formed into the elongate wire or core. As a result, the outer diameter of a platinum wire can more closely approximate the inner diameter of the tube. Thus it is to be appreciated that the optimum diameter values vary with the materials involved, and the expected length of the composite filament.

In any event, insertion of the core into the tube forms a composite filament **34**, which then is directed through a series of alternating cold-working and annealing steps, as indicated schematically in FIG. **6**. More particularly, composite filament **34** is drawn through three dies, indicated at **36**, **38**, and **40**, respectively. In each of the dies, composite filament **34** is cold-worked in radial compression, causing the case tube **32** and the tantalum core wire **28** to cold flow in a manner that elongates the filament while reducing its diameter. Initially, case tube **32** is elongated and radially reduced to a greater extent than core wire **28**, due to the minute radial gap that allowed the insertion of the core into the tube. However, the radial gap is closed rapidly as the filament is drawn through die **36**, with subsequent pressure within die **36** and the remaining dies cold-working both the core and case together as if they were a single, solid filament. In fact, upon closure of the radial gap, the cold-working within all dies forms a pressure weld along the entire interface of the core and case, to form a bond between the core and case material.

As composite filament **34** is drawn through each die, the cold-working induces strain hardening and other stresses within the filament. Accordingly, one or more heating stages are provided, e.g. furnace **42**. At each annealing stage, composite filament **34** is heated to a temperature in the range of from about 1900° to about 2300° F., or more preferably 2000°–2150° F. At each annealing stage, substantially all of the induced stresses are removed from the case and core, to permit further cold-working. Each annealing step is accomplished in a brief time, e.g. in as few as one to fifteen seconds at annealing temperature, depending on the size of composite filament **34**.

While FIG. **6** illustrates one cold-working stage and annealing stage, it is to be understood that the appropriate number of stages is selected in accordance with the desired final filament size, the desired degree of cross-sectional area reduction during the final cold-working stage, and the initial filament size prior to cold-working. In connection with composite filament **34**, a reduction of lateral cross-sectional area in the range of about forty percent to eighty percent is preferred, and a range of about fifty-five percent to sixty-five percent is highly preferred.

The successive cold-working and annealing steps give rise to the need for matching the core and case materials, particularly as to their coefficients of thermal expansion, elastic moduli in tension, annealing temperature ranges, total elongation capacities, and also as to their crystalline structure. A good match of elastic moduli, elongation, and thermal expansion coefficients minimizes the tendency for any ruptures or discontinuities along the core/case interface as the composite filament is processed. Crystalline structures should be considered in matching core and case materials. The Elgiloy alloy, and other materials used to form case tube **32**, commonly experience a transformation between the cold-working and aging steps, from a face centered cubic crystalline structure to a hexagonal close packed crystalline structure. The Elgiloy alloy experiences shrinkage as it undergoes this transformation. Accordingly, the core material must either experience a similar reduction, or be sufficiently ductile to accommodate reduction of the case.

There is no annealing after the final cold-working stage. At this point, composite filament **34** is formed into the shape intended for the device incorporating the filament. In FIG. **8**, several filaments or strands **34***a–e* are helically wound about a cylindrical form **48** and held in place at their opposite ends by sets of bobbins **50***a–e* and **52***a–e*. Strands **34***a–e* can be individually processed, or individual segments of a single annealed and cold-worked composite filament, cut after the final cold-working stage. In either event, the filaments cooperate to form one of the two oppositely directed sets of spaced apart and parallel filaments that form a device such as stent **16**. While only one set of filaments is shown, it is to be understood that a corresponding group of filaments, helically wound and intertwined about form **48** in the opposite direction, are supported by corresponding bobbins at the opposite filament ends.

A useful prosthesis depends, in part, upon correctly supporting the filaments. The filaments are maintained in tension, and it is important to select the appropriate tensile force and apply the tensile force uniformly to all filaments. Insufficient tensile force may allow wire cast or lift effects to cause the individual filaments to depart from their helical configuration when released from the bobbins, and the braided structure of the stent may unravel.

FIG. **9** illustrates two filaments **34***a* and **54***a*, one from each of the oppositely wound filament sets, supported by respective bobbins **50***a*/**52***a* and **56***a*/**58***a* in a furnace **60** for age hardening in a vacuum or protective atmosphere. Age hardening is accomplished at temperatures substantially lower than annealing, e.g. in the range of about 700°–1200° F., more preferably 900°–1000° F. The filaments overlie one another to form several intersections, one of which is indicated at **62**. When the filaments are properly tensioned, a slight impression is formed in the overlying filament at each intersection. These impressions, or saddles, tend to positionally lock the filaments relative to one another at the intersections, maintaining the prosthesis configuration without the need for welding or other bonding of filaments at their intersections.

While only two oppositely directed filaments are illustrated as a matter of convenience, it is to be appreciated that the age hardening stage is performed after the tensioning and winding of all filaments, i.e. both oppositely directed sets. Accordingly, during age hardening, the filaments are locked relative to one another at multiple intersections. The preferred time for age hardening is about 1–5 hours. This age hardening step is critical to forming a satisfactory self-expanding prosthesis, as it substantially enhances elasticity, yield strength, and tensile strength. Typically, the elastic modulus is increased by at least 10 percent, and the yield strength (0.02% offset) and tensile strength are each increased by at least 20 percent.

As an alternative to the process just explained, a substantially larger and shorter composite structure **64** (e.g. six inches long with a diameter of approximately two inches) can be subjected to a series of elongation and diameter reduction steps. FIG. **10** schematically illustrates two swaging dies **66** and **68**, which may be used in the course of a hot working billet reduction process. Of course, any appropriate number of swaging dies may be employed. Alternatively, the diameter reduction can be accomplished by extrusion/pulltrusion at each stage. When a sufficient number of swaging steps have reduced the composite structure diameter to about 6 millimeters (0.25 inches). The composite structure or filament can be further processed by drawing it through dies and annealing, as illustrated in FIG. **6** for the previously discussed process. As before, the composite filament is ready for selective shaping and age hardening after the final cold-working stage.

As compared to the process depicted in FIGS. **5–7**, the swaging or pulltrusion approach involves substantially increased hot and cold-working of the composite structure or filament, and the initial assembling of the core into the case or shell tubing is easier. Given the much larger initial composite structure size, the structure is subjected to annealing temperatures for a substantially longer time, e.g. half an hour to an hour, as opposed to the one to fifteen second anneal times associated with the process depicted in FIG. **6**. Consequently, particular care must be taken to avoid combinations of core and case materials with tendencies for intermetallic formation along the core/case interface. Further, the required hot working of the larger billet may not afford the same degree of metallurgical grain refinement.

FIG. **11** is an end elevation of a composite filament **74** including a central core **76** of a structural material such as the Elgiloy alloy, surrounded by a radiopaque case **78**, thus reversing the respective functions of the core and case as compared to composite filament **34**. Composite filament **74**, as compared to filament **34**, presents a larger and less refractive radiopaque profile for a given composite filament diameter. Composite filament **74**, however, may be more difficult to manufacture than filaments that employ the structural material as the case.

FIGS. **12** and **13** show a further alternative composite filament **80**, consisting of a central radiopaque core **82**, an outer annular structural case **84**, and an intermediate annular layer **86** between the core and the case. Intermediate layer **86** provides a barrier between the core and case, and is particularly useful in composite filaments employing core and case materials that would be incompatible if contiguous, e.g. due to a tendency to form intermetallics. Materials suitable for barrier layer **86** include tantalum, niobium and platinum. As suggested by FIG. **12**, the core, barrier layer and case can be provided as a cylinder and two tubes, inserted into one another for manufacture of the composite filament as explained above.

FIG. **14** illustrates another alternative embodiment composite filament **88** having a central radiopaque core **90**, a structural case **92**, and a relatively thin annular outer cover layer **94**. Composite filament **88** is particularly useful when the selected mechanical structure lacks satisfactory biocompatibility, hemocompatibility, or both. Suitable materials for cover layer **94** include tantalum, platinum, iridium, niobium, titanium and stainless steel. The composite filament can be manufactured as explained above, beginning with insertion of the radiopaque core into the structural case, and in turn, inserting the case into a tube formed of the cover material. Alternatively, cover layer **94** can be applied by a vacuum deposition process, as a thin layer (e.g. from ten to a few hundred microns) is all that is required.

The following examples illustrate formation of composite filaments according to the above-disclosed processes.

EXAMPLE 1

An elongate tantalum core having a diameter of 0.046 inches (1.17 mm) was assembled into an Elgiloy alloy case having an outer diameter of 0.102 inches (2.6 mm) and an inner diameter of 0.056 inches (1.42 mm). Accordingly, the lateral cross-sectional area of the tantalum core was about 25% of the composite filament lateral cross-sectional area. Composite filaments so constructed were subjected to 5–6 alternating stages of cold-working and annealing, to reduce the outer diameters of the composite filaments to values within the range of 0.004–0.0067 inches. The tantalum core diameters were reduced to values in the range of 0.002–0.0034 inches. The composite filaments were formed into a stent suitable for biliary applications, and age hardened for up to five hours, at temperatures in the range of 900°–1000° F.

EXAMPLE 2

Elongate cores of a platinum iridium alloy (20% by weight iridium), with initial core outer diameters of 0.088 inches, were inserted into annular Elgiloy cases with outer diameters of 0.098 inches and inside diameters of 0.044 inches. The resulting composite filaments were processed through about six cold-working and annealing cycles as in the first example, to reduce the outer filament diameter to values within the range of 0.00276 inches–0039 inches, and reducing the core outer diameter to values in the range of 0.0018–0.0026 inches. The core thus constituted 43% of the filament lateral cross-sectional area. The resulting filaments were formed into a small vascular stent, and age hardened for approximately three hours.

EXAMPLE 3

Composite filaments were constructed and processed substantially as in example 2, except that the core was formed of a platinum nickel alloy, with nickel 10% by weight.

EXAMPLE 4

The composite filaments were constructed and processed as in examples 2 and 3, except that the core was formed of tantalum, and the case was formed of MP35N alloy, and the cold-working stages reduced the filament outer diameter to values in the range of 0.00276–0.0047 inches.

In the case of all examples above, the resulting stents exhibited satisfactory elasticity and were readily fluoroscopically imaged in real time.

Each of the above described composite filaments combines the desired structural stability and resiliency, with radio-opacity that allows in vivo imaging of the device composed of the filaments, during deployment and after device fixation. This result is achieved by a drawn filled tubing process that cold works a central core and its surrounding case, to positively bond the core and case together such that the composite filament behaves as a continuous, solid structure. Performance of the filament and resulting device is further enhanced by a selective matching of the core and case materials, as to linear thermal expansion coefficient, annealing temperature, moduli of elasticity, and crystalline structure.

What is claimed is:

1. A body compatible device comprising:

a length of elongate filament substantially uniform in lateral cross-section and including an elongate cylindrical core and an elongate tubular case surrounding the core at least substantially over the length of filament, a lateral cross-sectional area of the core being at least about ten percent of a lateral cross-sectional area of the length of filament;

wherein one of the core and case is constructed of a first material having a linear attenuation coefficient of at least 25 cm^{-1} at 100 KeV, the other of the core and case is constructed of a second material, and the first material is more radiopaque than the second material; and

wherein the length of filament, due at least in part to a heating of the length of filament to a temperature of about 700° F. to about 1900° F. after a final annealing, exhibits (a) an at least 10 percent greater modulus of elasticity; (b) a greater yield strength at 0.2 percent offset; and (c) a greater tensile strength, as compared to an otherwise identical length of filament which has not been heated to a temperature of about 700° F. to about 1900° F. after a final annealing.

2. The device of claim **1** wherein the other of the core and case which is constructed of a second material has a yield strength of at least 150,000 psi at 0.2 percent offset and the first and second materials have about the same linear coefficients of thermal expansion.

3. The device of claim **1** wherein the core comprises the first material and the case comprises the second material.

4. The device of claim **1** wherein the case comprises the first material and the core comprise the second material.

5. The device of claim **1** wherein the first material has a direct or equivalent atomic number of at least fifty and a density of at least 0.5 pounds per cubic inch.

6. The device of claim **5** wherein the first material consists essentially of at least one of the following: tantalum, platinum, gold, iridium, rhenium, tungsten, ruthenium and depleted uranium.

7. The device of claim **1** wherein the second material consists essentially of at least one of the following: cobalt, chromium, titanium, aluminum, vanadium, chromium, nickel, molybdenum and iron.

8. The device of claim **7** wherein the second material consists essentially of a cobalt-based alloy.

9. The device of **8** wherein the cobalt-based alloy consists essentially of cobalt, chromium, iron, nickel, and molybdenum.

10. The device of claim **1** wherein a lateral cross-sectional area of the core is in the range of from ten to forty-six percent of the lateral cross-sectional area of the length of filament.

11. The device of claim **2** wherein both the first material and the second material have linear coefficients of thermal expansion within the range of about 3×10^{-6} per degree F. to about 9×10^{-6} per degree F.

12. The device of claim **1** wherein the length of filament, as compared to the non-heated length of filament, has a yield strength at 0.2 percent offset at least about 20 percent greater and a tensile strength at least about 20 percent greater.

13. The device of claim **1** wherein the greater modulus of elasticity is due at least in part to the heating while the length of filament is in a selected shape.

14. The device of claim **13** wherein the enhanced modulus of elasticity is due at least in part to a heating of the length of filament to a temperature of about 700° F. to about 1200° F. after a final annealing.

15. The device of claim **14** wherein both the first material and the second material have linear coefficients of thermal expansion within the range of about $3\times10-6$ per degree F. to about 9×10^{-6} per degree F.

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